CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
19-979/S-018

Chemistry Review(s)

DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: **19-979 SE1-018** Review #1 REVIEW DATE: March 28, 2001

Submission Type	Document Date	CDER Date	Content / Topics Covered
Amendment to Supplement (BL)	January 5, 2001	January 8, 2001 (HFD-110)	(1) Response to FDA's letter dated Nov 22, 2000 (2) Revised draft labeling
Amendment to Supplement (BF)	March 20, 2001	March 21, 2001	Final Printed Labeling

NAME & ADDRESS OF APPLICANT:

Hoffmann-La Roche Inc
340 Kingsland Street
Nutley, New Jersey 07110-1199
Phone (973) 562-3550

Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs
Phone (973) 562-5539
FAX (973) 562-3554

DRUG PRODUCT NAME

Trade Name: Ticlid ® Tablets
Nonproprietary name (USAN): ticlopidine hydrochloride
Code Name: RS-99847 CAS Number: 53885-35-1
Chemical Name: 5-(2-chlorobenzyl)-4,5,6,7-tetrahydrothieno-[3,2-c]pyridine HCl

AMENDMENT TO SUPPLEMENT contains Final Printed Labeling.

PHARMACOLOGICAL CATEGORY / INDICATION: Platelet inhibitor
DOSAGE FORM: Oral Tablet STRENGTH: 250 mg
ROUTE OF ADMINISTRATION: Oral DISPENSED: Rx

SUPPORTING DOCUMENT: CMC Review & T-con dated October 6, 2000 (attached)

REMARKS AND COMMENTS:

1) There are no CMC issues that require evaluation prior to approval of this efficacy supplement.
2) There are no changes to the How Supplied & Description Sections of the labeling.
3) Categorical exclusion from the requirement to prepare an Environmental Assessment is granted because entry concentration into the aquatic environment is not more than 1 ppb. [Reference: 21 CFR § 25.31 (b)]

CONCLUSION & RECOMMENDATION:

The supplement may be approved from a CMC perspective.

/S/

Florian W. Zielinski, Review Chemist, March 28, 2001

Distribution:
Orig. NDA 19-979 S-018
HFD-110 Division File
HFD-110 CSO, Colleen LoCicero

Initialed by Kasturi Srinivasachar

OCT 6 2000

LoCicero

DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #19-979 SEI-018 **CMC Review and T-Con: Oct. 6, 2000**

Submission Type	Date Received @ FDA	Content / Topics Covered
Efficacy Supplement	January 24, 2000	Exemption from EA requirement

NAME & ADDRESS OF APPLICANT:
Hoffmann-La Roche Inc
340 Kingsland Street
Nutley, New Jersey 07110-1199

Debra Iorio, Program Manager, Drug Regulatory Affairs, (973) 562-3550
Lynn DeVenezia-Tobias, Program Manager, Drug Regulatory Affairs, (973) 562-5539
Fax (973) 562-3700

DRUG PRODUCT NAME: Trade Name: Ticlid ® Tablets

SUPPLEMENT 18 provides for a new indication.

PHARMACOL. CATEGORY / INDICATION: Antiplatelet agent (Platelet inhibitor)

DOSAGE FORM: Oral Tablet STRENGTHS: 250 mg

ROUTE OF ADMINISTRATION: Oral DISPENSED: Rx

SUMMARY OF REMARKS/COMMENTS FROM THE T-CON: Hoffmann-La Roche Inc., Nutley, NJ requested and qualifies for, categorical exclusion from the requirement to prepare an EA. Approval of the Efficacy Supplement will increase the amount of active moiety used. However, the estimated concentration of the drug substance at the point of entry into the aquatic environment is less than 1 part per billion. Reference: CFR 21 § 25.31 (b)

CONCLUSIONS & RECOMMENDATIONS:
(1) The supplement, SEI-018, requests approval of a new indication for the drug product based on a review of the medical literature. As a result, there are no CMC issues that require evaluation prior to approval of this Supplement.
(2) Grant categorical exclusion from the requirement to prepare an Environmental Assessment

/S/ Oct 6, 2000

Florian W. Zielinski, Review Chemist
October 6, 2000

Distribution:
Orig. NDA 19-979 S-018
HFD-110 Division File
HFD-110 Florian Zielinski
HFD-110 CSO, LoCicero
Initialed by: K Srinivasachar

/S/ 10-6-00